

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 133

[Docket No. 2000P-0586] (formerly Docket No. 00P-0586)

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Contact N. Hawkins

Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to provide for the use of fluid ultrafiltered milk (UF) in the manufacture of standardized cheeses and related cheese products. This action responds principally to two citizen petitions: One submitted by the American Dairy Products Institute (ADPI) and another submitted jointly by the National Cheese Institute (NCI), the Grocery Manufacturers of America, Inc. (GMA), and the National Food Processors Association (NFPA). FDA tentatively concludes that this action will promote honesty and fair dealing in the interest of consumers and, to the extent practicable, will achieve consistency with existing international standards of identity for cheeses and related cheese products.

DATES: Submit comments by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: You may submit comments, identified by Docket No. 2000P-0586, by any of the following methods:

Electronic Submissions

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Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:

Division of Dockets Management (HFA-305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket Nos. or Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document,

into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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I. Background

The standards of identity for cheeses and related cheese products are specified in part 133 (21 CFR 133). The general provisions within part 133, in part, define “milk” and “nonfat milk” that may be used in the manufacture of cheeses and related cheese products. The definitions for “milk” and “nonfat milk” in § 133.3(a) and (b), respectively, list different forms of milk and nonfat milk, including concentrated, reconstituted, and dried forms, that may be used in the making of cheeses and related cheese products. However, fluid or dried filtered forms of milk obtained through mechanical filtration of milk or nonfat milk are not included within these definitions. Therefore, while current regulations permit the use of concentrated, reconstituted, and dried forms of milk and nonfat milk as basic dairy ingredients, they do not provide for the use of fluid or dried filtered milk or fluid or dried filtered nonfat milk as basic dairy ingredients in standardized cheeses and related cheese products.

Mechanical filtration technologies available for milk processing include microfiltration, ultrafiltration, nanofiltration, and reverse osmosis (Refs. 1 and 2). In all of these filtration methods, milk is passed over a series of semipermeable membranes with varying pore sizes. The portion of milk that passes through the membranes is referred to as the “permeate,” and the portion

that does not pass through the membranes is referred to as the “retentate.”

While the application of hydraulic pressure is the driving force for these membrane separation processes, the nature of the membrane itself (as well as the orientation of the components) controls which components of milk are separated into the permeate and which components are retained in the retentate during these filtration processes (Refs. 1 and 2). In a reverse osmosis (RO) filtration, the membrane pore size is such that all components other than water in the milk are retained. Nanofiltration uses membranes with pores that are larger than RO membranes, but smaller than those used in ultrafiltration. In milk processing, nanofiltration can be used to remove water as well as some soluble salts, yet retain all other components of milk (Refs. 1 and 2).

Ultrafiltration retains macromolecules and particles larger than about 0.001–0.02 micrometers, while microfiltration is designed to retain particles between about 0.10 micrometers to 5 micrometers (Ref. 1). While there is some overlap in membrane pore sizes and operating pressures used in ultrafiltration and microfiltration (Refs. 1 and 3), in dairy processing, ultrafiltration is typically used to retain all protein components of milk, including casein and whey proteins, while some of the lactose, minerals, and water soluble vitamins present in milk are lost along with water. Microfiltration, on the other hand, is primarily used for fat separation, bacterial removal, and casein concentration, with a resulting loss of whey proteins, lactose, minerals, and water soluble vitamins along with water (Refs. 1, 2, and 3).

A. Petitions and Grounds

FDA received two petitions requesting amendments to existing regulations to permit the use of filtered milk in the manufacture of standardized cheeses and related cheese products.

1. The 1999 ADPI Petition

The ADPI filed a citizen petition (CP) on December 2, 1999 (Docket No. 1999P-5198 (formerly Docket No. 99P-5198); hereafter referred to as the ADPI petition) requesting that the FDA amend the definition of “milk,” as provided in § 133.3(a), to include fluid UF milk, thereby permitting the use of fluid UF milk in the manufacture of standardized cheeses and related cheese products specified in part 133. ADPI requested that § 133.3(a) be amended to add that “milk may be subjected to an ultrafiltration process that results in a fluid UF milk for use in the manufacture of cheese.” In its petition, ADPI stated that the requested amendment would improve efficiencies in cheese manufacturing and result in benefits to consumers without alteration of cheese composition, characteristics, or flavor. FDA reviewed the ADPI petition and determined that it did not present reasonable grounds in accordance with 21 CFR 10.30 to support the requested amendment and, therefore, FDA closed this petition. However, because the issues raised in the ADPI petition are clearly covered under a second citizen petition (Docket No. 2000P-0586 (formerly Docket No. 00P-0586)/CP2, discussed in section I.A.2 of this document), FDA converted the ADPI petition into a comment to this second petition. ADPI was informed of FDA’s action in a letter dated February 26, 2003.

2. The 2000 NCI/GMA/NFPA Joint Petition

On June 13, 2000, FDA received a joint petition (Docket No. 2000P-0586 (formerly Docket No. 00P-0586)/CP2; hereafter referred to as the NCI petition) from the NCI, the GMA, and the NFPA requesting an amendment of § 133.3 to include “filtered milk” in the definition of “milk” and “filtered skim milk” in the definition of “nonfat milk” for use in standardized cheeses and related

cheese products. The NCI petition also requested that a new subsection be added within § 133.3 to define “filtered milk” as:

* * * the liquid milk product produced by a physical separation technique in which raw or pasteurized milk is passed over one or more semipermeable membranes to partially remove the water phase and its constituents, including water, lactose, whey proteins, and minerals. Either before or after filtration, fat may be separated to produce filtered skim milk. After filtration, water may be partially removed by means of evaporation to produce more concentrated forms of filtered milk.”

Based on this definition, FDA believes that the petitioners requested the agency to permit not only ultrafiltration (which typically does not result in a loss of whey proteins), but also other filtration techniques such as microfiltration and subsequent treatment to further concentrate the filtered product, in the manufacture of standardized cheeses and related cheese products. The petitioners withdrew a previous joint petition (Docket No. 2000P-0586 (formerly Docket No. 00P-0586)/CP1) that requested amendments to permit both fluid and dried forms of filtered milk in the manufacture of standardized cheeses and related cheese products.

In support of their requested amendments, the NCI, GMA, and NFPA (hereafter referred to as the petitioners) argued that the amendments requested in the NCI petition are consistent with established FDA policy. Some cheese standards, in addition to specifying a specific procedure for preparing the food, currently provide for the use of “any other procedure which produces a finished cheese having the same physical and chemical properties” (see e.g., standard of identity for cheddar cheese in § 133.113). The petitioners maintained that these “alternate make procedure” provisions historically have provided the legal basis for the use of milk filtration and the resulting filtered

milk in cheese making, regardless of whether the filtration occurs in the same plant as other cheese-making procedures or in a centralized filtration facility. The petitioners believe that FDA has previously acknowledged that the use of filtered milk to manufacture cheddar cheese is covered by the alternate make procedure provision of the standard of identity for cheddar cheese. Furthermore, the petitioners maintained that the requested amendments are fully consistent with the basis and rationale for amendments that FDA previously made to expand the scope of the forms of milk recognized as “milk” for cheese making. The petitioners stated that FDA authorized the use of certain forms of milk because these forms of milk may be used in place of fluid milk to produce a finished cheese that is equivalent physically and chemically to the traditional cheese made using fluid milk.

In addition, the petitioners stated that mechanical filtration has been used in cheese manufacturing in the United States for the past 20 years, and contended that the extensive use of filtration technologies, under the existing “alternate make procedure” provisions within some standards of identity for cheeses, has produced significant benefits by improving product consistency and yields and manufacturing efficiency; lowering milk refrigeration, hauling and whey disposal costs; expanding milk sourcing options; and enabling cheese makers to respond more effectively to regional disruptions in the fluid milk supply. The petitioners also stated that because mechanical filtration removes only those constituents that are removed by loss of whey in traditional cheese making, it functions simply to rearrange the steps in the cheese making process to permit the constituents to be removed earlier. The petitioners further contended that the long history and widespread use of filtration technology under the alternate make procedure provisions have clearly established the

equivalence of cheese made from filtered milk and cheese made from other forms of milk explicitly permitted under § 133.3.

The petitioners also argued that cheese made with filtered milk is nutritionally equivalent to traditional cheese because mechanical filtration of milk using membranes with pore sizes between 0.0001 and 0.20 microns removes the water phase constituents (water, soluble protein, lactose, minerals, and some water soluble vitamins) that otherwise would be removed in the traditional cheese-making process as whey. In fact, the petitioners argued, with respect to filtered milk in cheese, the retentate may actually contain slightly greater concentrations of valuable constituents (e.g., whey proteins) than the cheese curd that remains after loss of whey in traditional cheese making. The petitioners provided analytical data related to cheddar cheese to support their assertion that cheese made with filtered milk is not “nutritionally inferior,” as that term is defined in 21 CFR 101.3(e)(4), to cheese made using traditional procedures.

Finally, the petitioners argued that their proposed amendments are consistent with the Codex Alimentarius Commission (Codex) standard for cheese. The Codex standard for cheese (Standard A-6-1978, revised in January 1999) provides for the use of “milk and/or products obtained from milk.” The petitioners stated that the Codex standard encompasses mechanical filtration technology, provided the finished cheese meets applicable requirements for physical and chemical properties, which would include nutritional and organoleptic properties.

B. The Government Accountability Office (GAO)¹ Report

The fiscal year (FY) 2000 FDA appropriations bill from the U.S. Senate requested the Comptroller General to conduct a study to determine the quantity and end use of UF milk imported into the United States and to submit a report describing the results of the study to Congress. In March 2001, GAO reported (hereafter referred to as “the GAO report” (Ref. 4)), in part, that: There are no specific data on UF milk imports because UF milk is classified under the broad category of “milk protein concentrates” (MPC) by the U.S. Customs Service. GAO reported that imports in the broad category of MPC rose dramatically between 1990 and 1999 from about 800 to 45,000 metric tons, the primary reasons being the difference between U.S. and international prices of milk protein, especially nonfat dry milk (NFDM), and the market growth of nutritional supplements and other novel foods using MPC. GAO also reported that dry MPC imports are used in several foods other than cheeses, such as frozen desserts, bakery products, and sports and other nutritional supplement products. Some in the industry note that economic disincentives have prevented domestic production of dry MPC. GAO noted that there are limited data on domestic production and use of fluid UF milk in cheese making but found that 22 dairy plants produce fluid UF milk used to make cheese within the plant, while 4 dairy farms in New Mexico and Texas produce fluid UF milk for transport to cheese plants in the Midwest. GAO also found that FDA and State contract inspectors reported no violations related to the use of imported UF milk or MPC in standardized cheese in FY 1999, whereas in FY 2000, two plants in Vermont were issued warning letters for using

¹ The GAO changed its name from the “General Accounting Office” in 2004.

imported MPC in standardized cheese, and the plants subsequently discontinued this use.

C. Comments to Petitions

FDA received a total of 58 letters and e-mails, each containing one or more comments, to the ADPI (subsequently converted to a comment to the NCI petition) and the NCI petitions. A large portion of the letters and e-mails received were from individual dairy farmers, organizations representing dairy farmers, and consumers. Nearly half of the comments opposed both the ADPI and NCI petitions, while the other half opposed the NCI petition alone without commenting on the ADPI petition. A few comments expressed support for the ADPI petition, but none of the comments supported the NCI petition. The primary concern expressed by the comments opposing either of the petitions appeared to be the potential economic impact of the use of imported milk ingredients, particularly dried forms of filtered milk or MPC, on U.S. dairy farmers. Some comments also expressed concern about the use of imported milk ingredients on the quality and safety of cheese.

The organizations representing dairy farmers expressed strong opposition to both petitions and stated that the use of filtered milk would undoubtedly lower the quality of cheese products and greatly increase the flood of imports of subsidized MPC and filtered milk with the potential to jeopardize the safety of cheese products. They stated that the filtration process removes calcium and reduces the lactose content of milk and results in cheese that does not have the fullness of flavor of traditional cheese. They further maintained that changing the definition of milk to allow the use of liquid filtered milk would ultimately result in the use of dry filtered MPC and, therefore, they reiterated that even if only liquid filtered milk were allowed, while disallowing dry MPC,

they would still be concerned about product quality degradation. In addition, they stated that changing the definition of milk could result in increased imports of filtered milk from Canada, displacing U.S. milk and causing a surplus. However, these comments did not provide any factual data or information that would lead FDA to believe that the use of fluid UF milk would impact the safety or quality of the product.

Another comment, from an organization representing milk producers, unconditionally endorsed the ADPI petition, but strongly opposed the NCI petition, stating that the commenter does not support any change to § 133.3(a) that alters which products are currently defined as “milk.” This comment stated that the language in the NCI petition is sufficiently vague that it may be subject to interpretation such that it subsequently would allow dried forms of UF milk. The comment also stated that permitting only liquid forms of UF milk has general widespread support among different stakeholders, and argued that it is essential to establish a definition of “liquid” UF milk to mitigate potential misinterpretations regarding the use of dried MPC and provide clarity for enforcement. In this regard, the comment suggested that a limitation of 45 percent total solids be included in the definition of “liquid ultrafiltered milk,” because a requirement of a maximum of 45 percent total solids would allow for the use of UF technology while preserving the liquid state of the ultrafiltered product and preventing subsequent treatment for concentration beyond ultrafiltration.

D. Forms of Milk Permitted as Basic Dairy Ingredients

The definitions of “milk” and “nonfat milk” in § 133.3 do not provide for the use of filtered milk or filtered nonfat milk as basic dairy ingredients in standardized cheeses and related cheese products. In 1983, with respect to

the use of the forms of milk that are permitted as basic ingredients in cheesemaking, FDA amended § 133.3 to define the class designations “milk,” “nonfat milk,” and “cream” and provide for alternate forms of milk, nonfat milk, and cream, i.e., concentrated, dried, and reconstituted forms to be used in standardized cheeses and related cheese products (48 FR 2736, January 21, 1983). In the proposed rule, FDA advised of its opinion that these alternate forms can be used to produce the same cheese as produced from fluid cow’s milk (43 FR 42127 at 42128, September 19, 1978), which was the only form of milk permitted as the basic ingredient for cheese manufacture at that time. Filtered forms, however, are not included within “milk” or “nonfat milk” permitted in standardized cheeses and related cheese products.

In the NCI petition, the petitioners argued that the alternate make procedure that is provided for in some cheese standards historically has provided the legal basis for the use of milk filtration and the resulting filtered milk as an ingredient in cheese making. FDA does not agree with the petitioners. The alternate make procedure provision provides for the use of “any other procedure which produces a finished cheese having the same physical and chemical properties” as the procedure specified in the standard. For example, the procedure for making blue cheese described in § 133.106(a)(2) requires *Penicillium roquefortii* spores to be added to the curd. In a final rulemaking in 1983, in response to a comment that this requirement should be changed to permit the addition of spores to dairy ingredients rather than only to the curd, FDA noted that a change is not necessary because the procedure described in § 133.106(a)(2) may be modified as provided for in § 133.106(a)(1), which states that any other procedure may be used which produces a finished cheese having the same physical and chemical properties

(48 FR 2736 at 2739). Rather than restricting the manufacturing procedure to the one specifically described in the standard, this provision allows manufacturers to use alternate manufacturing procedures, but not alternate ingredients, provided the alternate manufacturing procedure does not adversely affect the physical and chemical properties of the cheese. However, the alternate make procedure provision does not permit the use of dairy or other ingredients that are not specifically provided for in the cheese standard. Therefore, the alternate make provision of current cheese standards allows manufacturers to appropriately process the basic ingredient milk during the cheese-making process. For example, the ingredient milk may undergo an additional step of ultrafiltration prior to being introduced into the cheese vat in a single within-batch and within-plant production line for cheese making. In such a process, the ingredient that is introduced into the cheese-making process is milk. However, fluid UF milk purchased or brought in from another plant, even within the same company, that is then introduced into cheese making is considered an alternate ingredient because the ultrafiltration process is used solely for the production of an ingredient that is subsequently used in cheese making. Therefore, in this case, the ingredient is fluid UF milk, not milk.

In the NCI petition, the petitioners also stated that FDA has previously acknowledged that the use of filtered milk to manufacture cheddar cheese is covered by the alternate make procedure provision of the cheddar cheese standard, including when filtration occurs in a separate centralized facility. FDA clarifies that it has previously not objected to the use of fluid UF milk in cheddar cheese under specific circumstances. In 1996, FDA granted temporary permission to Bongards Creamery in Minnesota to manufacture

cheddar cheese using fluid UF milk that is produced on a farm in New Mexico. That permission was granted on a limited basis in response to a request from the T.C. Jacoby & Company, Inc., to run a testing program at Bongards Creamery during a pilot period to demonstrate that the finished cheddar cheese made with fluid UF milk as an ingredient has the same physical and chemical characteristics as traditional cheddar cheese (Ref. 5). In its response to T.C. Jacoby & Company, Inc., FDA stated that based on its understanding that “cheddar cheese produced with the retentate that results when milk is subjected to processing in a ultrafiltration system is nutritionally equivalent to and is physically and chemically identical” to cheddar cheese prepared by the standardized procedure, it would not object to the use of fluid UF milk in the manufacture of cheddar cheese at Bongards Creamery on the limited basis described by T.C. Jacoby & Company, Inc. (Ref. 6).

Subsequently, FDA stated its interpretation of the cheese standards that, as written, they do not allow for the use of UF milk as an ingredient (Ref. 7). FDA reaffirms that the use of filtered milk, dried or fluid, including fluid UF milk, as an ingredient is not covered under the alternate make procedures provided for in certain standardized cheeses. However, while FDA has considered the use of UF milk in standardized cheeses, it has stated that it would not object to the experimental use of fluid UF milk as an ingredient in cheddar and mozzarella cheeses (Ref. 7) and that enforcement regarding the use of UF milk as an ingredient in Swiss cheese is not a priority (Ref. 8).

Substances commonly referred to as MPC are also not permitted as ingredients in standardized cheeses. While there is no current FDA regulation that defines “MPC” and this term does not appear to have a standard definition within the industry, the term “MPC” is generally used to refer to dried forms

of filtered milk and dried blends and coprecipitates of milk proteins (Ref. 9). The existing standards of identity in part 133 do not list MPC as a permitted optional ingredient in the manufacture of standardized cheeses or related cheese products. Ingredients that are not specifically provided for by the standard cannot be used in the manufacture of a food named with the standardized term. FDA reiterated this statement in 1983 when FDA amended the standards for nine natural cheeses to bring them into closer conformance with the recommended Codex standards for those cheeses (48 FR 2736). FDA advised that dairy ingredients that may be used in manufacture of standardized cheeses are specifically listed in the individual standards, and that milk-derived ingredients other than those specifically provided for may not be used in these cheeses (48 FR 2736 at 2737). In addition, specific to the use of caseinates in standardized cheeses, FDA previously addressed comments on the use of caseinates in previous rulemakings (48 FR 2736 at 2737 and 58 FR 2431 at 2439, January 6, 1993), and advised that caseinates are not among the dairy ingredients provided for use in the manufacture of standardized cheeses in part 133 and, therefore, cannot be used. FDA reaffirms that ingredients other than those specifically provided for by the individual standards cannot be used in the making of standardized cheeses and related cheese products.

Therefore, under the current regulations, use of filtered milk, including fluid UF milk, as an ingredient in a cheese whose applicable standard(s) does not provide for its use would constitute a deviation from the standard, and such cheese cannot be named by the standardized term. However, under the provisions of 21 CFR 130.17, food manufacturers may request from FDA a temporary marketing permit (TMP) to market a food that is named by the standardized term but that deviates from its standard of identity.

E. Temporary Marketing Permit (TMP)

On August 1, 2002, FDA received an application from Wells' Dairy, Inc. (Wells' Dairy), for a TMP for the use of UF milk in the manufacture of cottage cheese. In the **Federal Register** of December 9, 2004 (69 FR 71418), FDA announced the issuance of a TMP to Wells' Dairy to market test cottage cheese that deviates from the standard of identity for cottage cheese in that the product is formulated using fluid UF skim milk. For the purpose of this TMP, fluid UF skim milk was described as "the product obtained by subjecting skim milk to a physical separation process called ultrafiltration using a membrane with a pore size of 10,000 Daltons (Da) molecular weight cut-off (MWCO), resulting in the partial loss of lactose, minerals, water-soluble vitamins, and water present in skim milk." The TMP also specified that the casein-to-whey protein ratio of skim milk is not altered during the ultrafiltration process and that the moisture content of fluid UF skim milk is about 80 percent. The TMP permitted the addition of such fluid UF skim milk to skim milk at a level needed to increase the total solids of the cheese milk (or final milk used to make cheese) by 5 to 25 percent, and required fluid UF skim milk to be declared in the ingredient statement of the finished cottage cheese as "ultrafiltered skim milk." The purpose of the permit was to allow Wells' Dairy to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility. The permit provided for the temporary market testing of 15 million pounds (lb) (6.8 million kilograms) of the test product for a period of 15 months.

II. The Proposal

A. Legal Authority/Statutory Directive

Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341)) directs the Secretary of Health and Human Services (the Secretary), to issue regulations fixing and establishing reasonable definitions and standards of identity, quality, or fill of container whenever such action will promote honesty and fair dealing in the interest of consumers. Section 701(e) of the act (21 U.S.C. 371(e)) directs the Secretary to publish a proposal for the amendment or repeal of any definition and standard of identity under section 401 of the act for any dairy product (e.g., cheese) that is based on a petition of any interested persons showing reasonable grounds.

B. Options Considered

FDA considered several options in response to the two petitions, including the following: (1) Denying the two petitions, (2) proposing to permit the use of all fluid forms of filtered milk, (3) proposing to permit the use of all fluid and dried forms of filtered milk, and (4) proposing to permit the use of fluid UF milk. FDA concluded that the first option would not be appropriate given that the NCI petition includes within its scope allowing the use of UF milk in standardized cheeses, which FDA tentatively concludes, for reasons discussed under option 4, should be permitted.

The second option, to provide for the use of all fluid forms of filtered milk in standardized cheeses, was also determined to be inappropriate. Standards of identity regulations establish the name of the food, which identifies and describes the food's basic nature (43 FR 42118 at 42120, September 19, 1978). As FDA discussed in 1950 during the establishment of the cheese standards of identity, the starting point for all varieties of cheese is milk. In preparing

milk for use in cheese making, adjustments may be made by adding or removing milk fat in the form of cream, fresh skim milk, NFDM solids, or concentrated skim milk so that the ratio of milk fat to the nonfat milk solids is at a desired level (15 FR 5656 at 5657, August 24, 1950). FDA reiterates its longstanding interpretation that a basic nature of cheese is that it is a food made using milk as the starting ingredient. Proposing to allow the use of all fluid forms of filtered milk in standardized cheeses was rejected because some forms of filtration concentrates are specific individual components of milk resulting in a retentate that is no longer milk. For example, microfiltration can be used to separate whey proteins along with lactose, minerals, and water-soluble vitamins from milk resulting in the concentration of casein fractions. FDA tentatively believes that such products that are merely concentrates of certain individual milk components are not milk. The use of individual components of milk, such as specific milk proteins, as the basic or starting ingredient in cheese is not consistent with the basic nature of cheese in that cheese is a food prepared using milk, not specific individual components of milk. Moreover, as FDA previously noted, when providing flexibility for use of advances in food technology, food standards should ensure that the basic nature of the food remains essentially the same (60 FR 67492 at 67499, December 29, 1995). FDA tentatively concludes that allowing for the use of technologies that could potentially result in the use of a specific component of milk as the starting ingredient of cheese would seem to violate the intent of the cheese standards of identity to preserve the basic nature of cheese.

In the NCI petition, the petitioners also stated that because mechanical filtration removes only those constituents that are removed by loss of whey in traditional cheese making, it functions simply to rearrange the steps in the

cheese-making process to permit the constituents to be removed earlier. FDA believes that food standards should provide for flexibility in manufacturing procedures and ingredients, provided that the basic nature and essential characteristics of the food are preserved. In determining which filtered products are appropriate for use as ingredients in cheeses, FDA considered how the use of a type of filtered milk affects the basic nature and essential characteristics of cheese. While filtration selectively and variably removes different constituents of milk that are lost, to varying degrees, during the whey removal process in the traditional cheese-making process, we do not agree that this fact can form a sufficient basis to support the use of all forms of fluid filtered milk as ingredients. Some forms of filtration result in retentates that are specific individual components of milk and are no longer milk. In addition, research suggests that milk that is concentrated to higher levels of protein is not suited for use in all types of cheeses, with adverse effects on quality being reported particularly in the case of hard and semi-hard cheeses (Refs. 1, 10, and 11). Moreover, FDA believes that in determining the appropriateness of different forms of filtered milk as ingredients in cheese a primary criterion, based on a fundamental principle of food standards, is whether the use of the filtered milk ensures the integrity of the standardized cheese—its basic nature and essential characteristics. As explained in the previous paragraph, FDA tentatively concludes that the use of a product of microfiltration as the starting ingredient of cheese is not consistent with the basic nature of cheese. Therefore, we do not agree that it is appropriate to provide for the use of all types of fluid filtered milk nor do we agree that the argument about the “rearrangement” of the steps of cheese making (as described by the petitioners)

sufficiently supports the appropriateness of the use of all forms of fluid filtered milk an ingredient.

A third option that was also considered inappropriate was to provide for all filtered milk, including both fluid and dried forms. Under this option, substances such as MPC, dry microfiltered (MF) milk, and caseins would be permissible in standardized cheeses or related cheese products. FDA's concerns regarding the use of all fluid filtered milk, which are stated in the two previous paragraphs, also apply to the use of dried filtered milks. Allowing for the use of technologies that could potentially result in the use of specific components of milk, such as caseins, rather than milk, as the starting ingredient of cheese would be inconsistent with the basic nature of cheese.

C. Proposed Amendments

Based on all the information available, including the information presented by the two petitions and the comments received thus far, FDA is proposing to amend the definitions of "milk" and "nonfat milk" in § 133.3 to do the following: (1) Provide for ultrafiltration of milk and nonfat milk and (2) define UF milk and nonfat milk as raw or pasteurized milk or nonfat milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein-to-whey protein ratio of the milk and resulting in a liquid product. FDA is also proposing that the name of such treated milk is "ultrafiltered milk" or "ultrafiltered nonfat milk," as appropriate. Consequently, when this type of milk is used, it would be declared in the ingredient statement of the finished food as "ultrafiltered milk" or "ultrafiltered nonfat milk."

First, providing for the use of fluid UF milk is consistent with the basic nature of cheese in that the starting ingredient is milk. During the process of

ultrafiltration, some of the lactose, soluble salts, and water-soluble vitamins of milk pass through the membranes and are removed, while protein, fat, fat-soluble vitamins, and some of the insoluble salts are retained. Therefore, unlike microfiltration, ultrafiltration does not result in the separation of specific fractions of milk proteins.

Second, FDA tentatively concludes that fluid UF milk can be used in standardized cheeses while maintaining the essential characteristics of these cheeses specified in the individual standards of identity in part 133. Scientific literature suggests that fluid UF milk, especially at low concentration factors, can be used in different cheeses (including soft, semi-hard, hard, and direct-acidified cheeses and process cheese) without adversely affecting the physical, chemical, or organoleptic properties of the cheese (Refs. 1, 2, and 11 through 20; Appendix F of the NCI petition). This appears to be especially true with soft cheeses such as cottage cheese (Refs. 1, 14, and 15) and some direct-acidified cheeses (Ref. 12). Specifically with respect to cottage cheese, as noted in section I.E of this document, FDA reviewed relevant scientific information related to the use of fluid UF milk as an ingredient and determined that fluid UF milk may be used in cottage cheese without adversely affecting the essential physical or chemical characteristics, including nutritional composition and organoleptic properties of cottage cheese. FDA issued a TMP to Wells' Dairy to market test cottage cheese that deviates from the standard of identity for cottage cheese in that the product is formulated using fluid UF skim milk (69 FR 71418).

FDA notes, however, that the scientific literature also includes some reports of adverse effects from the use of fluid UF milk on the texture and development of flavor and aroma of certain cheeses, particularly in semi-hard

and hard cheeses and with the use of fluid UF milk at higher concentration factors (Refs. 1, 11, 17, and 21 through 24). FDA points out that the use of fluid UF milk must not adversely affect the physical or chemical characteristics of the cheese. The cheese standards of identity ensure the integrity of the cheese by setting limits on its fat, milk solids-not-fat, and moisture content. In addition, FDA considers nutritional equivalency and organoleptic properties of the cheese among other factors to determine whether the essential characteristics of the cheese are maintained. Providing for the use of fluid UF milk does not preclude a standardized cheese from meeting the existing requirements within the applicable individual standard(s) of identity in part 133. Rather, the use of fluid UF milk would be optional and any cheese made using fluid UF milk would have to meet all the requirements, including the physical and chemical characteristics, specified in the applicable individual standard(s) of identity.

Third, FDA anticipates that providing for the use of fluid UF milk would enable cheese manufacturers to benefit from advances in milk filtration technology and provide them with greater flexibility in cheese making, while preserving the basic nature and essential characteristics of standardized cheese. Further, using ultrafiltration technology may result in better retention of milk proteins and greater cheese yields as well as more uniform product quality (Ref. 1). In addition, the petitioners claimed that using fluid filtered milk (including fluid UF milk) helps manage seasonal imbalances in milk supplies and demand for cheese, and reduces the costs associated with bulk milk distribution, resulting in cost savings that ultimately could be passed on to consumers. Furthermore, declaring fluid UF milk in the ingredient statement of the cheese as “ultrafiltered milk” or “ultrafiltered skim milk,” as

appropriate, would enable consumers to identify cheeses made with milk that has undergone ultrafiltration.

Finally, providing for the use of fluid UF milk would bring the standards of identity for cheeses in closer conformity with the international standards adopted by Codex and facilitate increased harmonization. In response to the ADPI and NCI petitions, FDA considered the relevant Codex standards for cheeses and related cheese products. Specifically, FDA reviewed the Codex standards for cheese (Codex Stan A-6), cheeses in brine (group standard) (Codex Stan 208), cottage cheese including creamed cottage cheese (Codex Stan C-16), cream cheese (Codex Stan C-31), extra hard grating cheese (Codex Stan C-35), unripened cheese including fresh cheese (group standard) (Codex Stan 221), named variety process(ed) cheese and spreadable process(ed) cheese (Codex Stan A-8(a)), process(ed) cheese and spreadable process(ed) cheese (Codex Stan A-8(b)), process(ed) cheese preparations (Codex Stan A-8(c)), and whey cheeses (Codex Stan A-7) (Refs. 25-34). FDA notes that several Codex standards such as the standard for cheese, group standard for cheeses in brine, and group standard for unripened cheese including fresh cheese all permit the use of "milk and/or products obtained from milk," which encompasses fluid UF milk, as the raw material in the manufacture of these cheeses, provided the finished cheese meets the relevant physical and chemical properties. Additionally, the Codex standard for whey cheeses provides for the addition of "raw materials of milk origin," including fluid UF milk. Providing for the optional use of fluid UF milk as a basic dairy ingredient in cheeses would be consistent with, although not as expansive as, the provisions of some Codex standards.

In a recent proposed rule (70 FR 29214, May 20, 2005) (the food standards proposal), FDA and FSIS proposed a set of general principles that define how modern food standards should be structured. The agencies also proposed that, if finalized, the agencies will require that a CP for establishing, revising, or eliminating a food standard be submitted in accordance with these general principles. Conversely, the agencies proposed that they may find deficient a petition to establish, revise, or eliminate a food standard that does not follow these general principles. FDA believes that the action proposed here to provide for the use of fluid UF milk as an ingredient in standardized cheeses and related cheese products is consistent with the general principles proposed in the food standards proposal.

For the reasons explained previously in this section, FDA tentatively concludes that providing for the use of fluid UF milk only, rather than for the use of all fluid filtered milk (as requested by the NCI petition), would promote honesty and fair dealing in the interest of consumers by providing greater flexibility in cheesemaking while preserving the basic nature and essential characteristics of the food. Therefore, FDA proposes to amend the definitions of “milk” and “nonfat milk” within § 133.3 to do the following: (1) Provide for ultrafiltration of milk and nonfat milk and (2) define UF milk and nonfat milk as raw or pasteurized milk or nonfat milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein-to-whey protein ratio of the milk and resulting in a liquid product. FDA also proposes that the name of such treated milk is “ultrafiltered milk” or “ultrafiltered nonfat milk,” as appropriate. Consequently, when this type of milk is used,

it would be declared in the ingredient statement of the finished food as “ultrafiltered milk” or “ultrafiltered nonfat milk.”

FDA seeks comment on the appropriateness of the proposed amendments, including the provision to permit the use of fluid UF milk and fluid UF nonfat milk. The proposed amendments would allow for optional ultrafiltration of the starting ingredient, milk or nonfat milk, used in cheese manufacturing. Under these proposed amendments, whether a manufacturer uses fluid UF milk is optional and entirely up to the manufacturer.

FDA also seeks comment on the appropriateness of the proposed definition of ultrafiltration. With respect to the requirement for an unaltered casein-to-whey protein ratio during ultrafiltration, FDA acknowledges that some loss of small molecular weight whey proteins may occur during ultrafiltration of milk with the extent of loss partially dependent on the nature of the membrane and the orientation of the molecules in milk (which may be influenced by the treatment of milk prior to or during ultrafiltration). While casein and most whey proteins are retained in the retentate, proteose-peptones with low molecular weights may be lost in the permeate. Proteose-peptones have a molecular weight between 4,100 and 20,000 Da (Ref. 35). Because there is expected to be free cross-flow of these proteins across the membranes, the loss of the very low molecular weight proteose-peptones may be small and, therefore, as noted in published reviews, the casein-to-whey protein ratio of milk would not be significantly altered during ultrafiltration (Refs. 36 and 37). Studies also have demonstrated complete retention of whey proteins and a relatively constant casein-to-whey protein ratio in milk that has been ultrafiltered to increasing volume concentration (Refs. 13, 38, and 39). The information presented by Wells' Dairy, Inc., as part of its TMP submission also

demonstrates that there is minimal, insignificant loss of true protein in the ultrafiltration permeate resulting in an ultrafiltered retentate with its casein-to-whey protein ratio intact (Docket No. 2004P-0519; 69 FR 71418).

FDA notes that a comment received in response to the two petitions suggested that any definition of ultrafiltration also include a requirement that the fluid UF milk must contain a maximum of 45 percent total solids (or a minimum moisture content of 55 percent). The comment stated that this requirement is necessary to define "liquid" UF milk and preclude any treatment following ultrafiltration to further concentrate UF milk. However, the comment did not provide any supporting information or data on the appropriateness of this minimum level of moisture. In the proposed definition of UF milk, FDA is not proposing a requirement related to minimum moisture content of UF milk; however, the proposed definition states that UF milk is a liquid product. FDA seeks comment on whether there is a need for an added measure to ensure the liquid nature of this ingredient and/or to preclude any subsequent treatment following ultrafiltration to further concentrate the fluid UF milk. If so, does a minimum moisture content requirement sufficiently address this concern and what is an appropriate minimum level of moisture?

FDA also seeks comment on the need for, and appropriateness of, the following: (1) Not permitting other forms of mechanical filtration, such as microfiltration; and (2) the requirement that the casein-to-whey protein ratio remain unaltered during ultrafiltration and the feasibility of such a requirement for compliance and enforcement purposes. If the requirement that the casein-to-whey protein ratio remain unaltered is not appropriate, FDA seeks information on what constitutes an acceptable variation of this ratio during

ultrafiltration of milk so that FDA may determine appropriate criteria for purposes of enforcement.

In response to the petitions, FDA received some comments that opposed the use of any filtered milk, citing product safety and quality concerns; however, these comments did not provide any scientifically sound and valid data to support their objections specifically with regard to fluid UF milk. At this time, FDA does not have any information that raises food safety concerns with the use of fluid UF milk in standardized cheeses. FDA specifically requests that any comments that address the technical aspects of these proposed provisions include sound scientific and factual data or information that support the positions presented in the comments. For example, are there analytical data or other information that would support a determination that standardized cheeses made using fluid UF milk, as defined in this proposed rule, are potentially unsafe or are nutritionally inferior? Are there scientific data or information that demonstrate that the use of fluid UF milk, as defined in this proposed rule, adversely affects the physical, chemical, or sensory characteristics of a particular standardized cheese or cheese product or that would support the determination that the use of fluid UF milk is not appropriate in a particular standardized cheese or cheese product?

III. Executive Order 12866: Cost Benefit Analysis

FDA has examined the economic implications of this proposed amendment for part 133 as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive

impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

A. Need for Regulation

Under current standards of identity for cheese and cheese products, the definitions of “milk” and “nonfat milk” do not encompass “filtered milk”. As a result, while these definitions list milk, nonfat milk, and the different forms (including concentrated, reconstituted, and dried) that can be used in making standardized cheeses, they do not explicitly permit the use of filtered milk as an ingredient in standardized cheeses. The use of filtered milk in cheese making provides greater flexibility and potential cost savings to cheese producers while still preserving the basic nature and essential characteristics of the food. FDA tentatively concludes that revision of the standard is needed to promote honesty and competition in the interest of consumers and to allow dairy producers to utilize a safe and effective technology.

B. Background and Current Industry Practices

The sources for this analysis were compiled from food research and chemistry journals, milk and cheese industry publications, U.S. Department of Agriculture (USDA) data and reports, other government agency reports, and expert opinions. Sources cited in this text refer to the specific passage or data reported, but all sources found at the end of the document were used to formulate the basis of the analysis.

The standardization of casein and fat content in milk is a common practice in cheese production that improves the consistency of the final products, reduces the volatility of total milk ingredient costs, and increases the amount of cheese produced per vat (Ref. 9). Not all cheese producers standardize their milk, but the amount of protein, specifically in the form of casein, present in milk for cheese production is the single largest factor affecting cheese yield. Condensed skim milk and NFDM are widely used to increase the amount of casein in cheese milk (Refs. 9 and 40). In 2001, the dairy industry purchased 621 million lb of NFDM, 67.5 percent of all domestic sales of NFDM. The use of NFDM in hard cheeses made up 43.3 percent of the total amount purchased by the dairy industry, and cottage and cream cheeses accounted for an additional 6.2 percent (Ref. 41).

By adding condensed milk or NFDM the cheese producer is adding lactose and minerals that must later be removed from the curd at a greater rate than the casein that provides the benefits (Ref. 40). Ideally, cheese producers would standardize their cheese milk with a higher concentration of protein without adding components that later have to be removed. The key components of milk products used in cheese making are listed in table 1 of this document.

TABLE 1.—COMPOSITION OF MILK PRODUCTS

Component ¹	Milk (%)	Nonfat Dry Milk (%)	Fluid UF Milk (%)	Dry UF Milk (%)	Fluid MF Milk (%) ²	Isolated Casein (%)
Protein	3.3	36	4.48–11.94	42–80	7.9	89–94
Fat	3.65	0.8	5.51–14.68	1–2.5	10.5	1.5 ³
Lactose	4.75	52	4.59–3.68	46–4.1	4.7	0–0.2 ³

¹ Percentages compiled from the Wisconsin Center for Dairy Research and the Wisconsin Milk Marketing Board White Paper (2001), Fassbender (2001), Innovations in Dairy (2001), and GAO (2001).

² As in the case of fluid UF milk, the composition of fluid MF milk can vary but we were unable to find a range of values of protein, fat, and lactose content of fluid MF milk in the literature.

³ Maximum values.

Table 1 of this document, reflects the fact that UF milk can be concentrated to a greater or lesser extent to meet the needs of different manufacturing processes. For some cheeses, the UF milk can be highly concentrated then

mixed with cream to produce a liquid "precheese" with the same gross composition as the final cheese. It has been shown that this precheese can be used in continuous process cheese making without the use of vats (Refs. 10 and 42). Some soft cheeses, processed cheese, and direct acidified cheese, particularly those made from goat's and sheep's milk, have been reported to be successfully produced using highly concentrated UF milk (Refs. 12, 13, and 43). However, the high concentration of the retentate may affect some properties of the milk and require specially designed equipment (Ref. 2).

More widely accepted for the common styles of cheese consumed in the United States appears to be the use of lower concentrations of UF milk to standardize the protein concentration in cheese milk to produce higher final cheese yields (Refs. 4, 10, and 44). Low concentration UF milk replaces a percentage of milk, usually between 10 and 20 percent, to provide a higher level of casein in the cheese milk without the addition of lactose and minerals (Ref. 40). Most of the benefits of using UF milk are from standardizing the protein concentrations while still allowing conventional cheese-making equipment to be used, or easily adapted for use (Ref. 10). Other uses include UF milk replacement to eliminate the natural seasonal variation in milk quality, improving the consistency of cheese (Ref. 9).

For the purpose of the economics analysis, and without making any declarations about what FDA believes is technically sufficient, we use a low concentration of UF milk with approximately 10 percent replacement as the appropriate reference for 80 percent of all cheese made in the United States. This is based on research that suggests that low concentration replacement has been successfully used in Cheddar and Mozzarella cheeses (Refs. 1 and 9), whereas continuous process cheese-making from high concentration UF milk

was not (Ref. 9). These two cheeses alone made up two-thirds of domestic cheese production in 2002 with Swiss and other American cheeses, making up an additional 13 percent (Ref. 45). If this proposed rule is finalized, all standardized cheese made in the United States, regardless of the variety and including those that implement UF technology, must continue to meet the physical and chemical properties specified in the standard.

Amending the standard of identity of cheese has the potential to affect two related sectors of the dairy industry: Dairy processors and cheese producers. Milk is produced on dairy farms daily, with the volume and composition varying both seasonally and daily. The milk is picked up from dairy farms and transported by milk haulers to cooperatives or proprietary operations for distribution or further processing. Large dairy farms may encompass production, processing, and even hard-product manufacturing facilities all at one site, whereas other dairy farms may belong to a cooperative or sell their milk to a proprietary operation that processes or further distributes the milk at its own discretion. Except in the cases of large operations, dairy farms do not usually process their own milk. Therefore, while there are almost 92,000 dairy operations (an operation is a place with one or more milk cows; a farm may include more than one operation) in the United States (Ref. 46), the unit of measurement for purchasing UF technology is the dairy processor who collects milk from one or more dairy operations. In addition to making the capital investment in UF technology, dairy processors would benefit from the decreased costs for transporting and storing UF milk during shipment to cheese producers.

Cheese producers, while not the direct purchasers of UF technology, would still be affected by the changes in the definition of milk in standardized

cheese if they choose to replace some of their ingredient milk with UF milk. Many of the benefits of using UF milk in cheese accrue to the cheese producers directly, including, e.g., higher cheese yields and increased production efficiency as well as a greater ability to eliminate the natural variation in their milk supplies, and reduced storage costs.

Dairy processors and cheese producers are not mutually exclusive categories. A dairy processor is a manufacturer of dairy products made using milk as the main dairy ingredient. Therefore, cheese producers are all dairy processors, but not all dairy processors produce cheese. In 2002 there were 403 cheese plants and 1,153 dairy processors in the United States (Ref. 45). Some dairy processors either manufacture cheese directly or manufacture dairy products that are sold to cheese producers. However, some dairy processors produce no cheese products or ingredients whatsoever, and instead, produce a variety of other dairy products including fluid milk, butter, ice cream, and whey products. It is also worth noting that dairy processors include cooperatives. In 1997 there were 226 dairy cooperatives that ranged in primary function from bargaining-only to hard-product manufacturing and fluid processing (Ref. 47).

We measure benefits as the net decrease in the cost of producing cheese. These benefits accrue from all types of protein-standardization; however, the extent of the benefits will vary depending on the milk product used. These benefits lead to cost savings that could be passed along to consumers if the market is opened to a larger number of dairy producers within the industry and competition among cheese producers is enhanced. When only those milk processors that are large enough to incorporate UF technology in legitimate alternate-make procedures (i.e., within plant and within batch) are allowed to

use the cost-saving technology in standardized cheeses, they will be able to sell their goods at the market price, which is based on competition among firms with higher production costs. If, however, the market is broadened so that all firms, large and small, are able to use the cost-saving technology, competition among these firms should bid down the market price of cheese, passing the savings on to consumers.

We measure the costs of using filtered milk to make standardized cheese as losses to consumers who prefer cheese made under the existing milk definitions, domestic and international market adjustments, and government purchases required under USDA's Commodity Credit Corp., program. Increases in government purchases of dairy products will not incur unless the market prices of specific products fall below the government floor prices.

C. Regulatory Options

We analyze several options for amending the standards of identity for cheeses and cheese products. Option 1 would amend the definition of milk in the standards of identity for cheeses to allow fluid UF milk to be used. Option 2 would allow fluid UF milk and dry UF milk. Option 3 would amend the definition of milk in the standards of identity for cheese to allow all filtration methods that resulted in a fluid milk product to be used in cheese production. Option 4 would allow all filtration methods that resulted in fluid or dry milk products to be used. Option 5 would allow all milk or products obtained from milk to be used in cheese production, in concert with the Codex general standard for cheese.

We estimate the benefits and costs of the regulatory option compared with the benefits and costs of a baseline. The baseline reflects the state of the industry before any new regulation is put in place. Therefore, in this analysis

the baseline is leaving the standard of identity for cheese unmodified, i.e., milk, nonfat milk, and the concentrated, reconstituted, and dried forms of milk and nonfat milk are the only basic ingredients allowed in the production of standardized cheese. Due to the “extensive use of nonfat dry milk (NFDM) as an ingredient for cheese manufacture in the United States” (Ref. 9), the baseline assumes NFDM is used as the source of supplemental solids in cheese manufacture. For purposes of this analysis, we assume that the benefits and costs of the baseline are zero.

Option 1: Allow fluid UF milk to be used in the making of standardized cheeses

This option would allow fluid UF milk to be used in the making of standardized cheese. For most U.S. cheese production, this option would result in replacing a percentage of the milk used in the production of cheese with fluid UF milk. This option differs from the baseline by substituting fluid UF milk for NFDM as the protein-dense replacement milk ingredient.

Benefits of Option 1: Fluid UF milk retains more moisture from milk than NFDM does, so as a percentage of total composition, UF milk has less protein than NFDM. However, it also contains less lactose than either NFDM or milk. In fact, the more highly concentrated the milk is, (the concentrations listed in table 1 of this document, vary from 1.5 to 4 times the solids concentration of milk), the more protein is retained and the less lactose is unnecessarily added. Replacement of milk with fluid UF milk during the manufacturing process produces yield increases per vat, thus spreading out fixed costs (labor, equipment, physical facility) over more total weight of cheese (Ref. 9). According to the Technical Director of North American Milk Products, a cheese plant that replaces 10 percent of its daily milk inputs with fluid UF skim milk would see an increase in cheese yield of 12 percent. This increase in yield

lowers costs by up to two cents per pound of cheese (Ref. 48). In 2002, 8.6 billion pounds of cheese were produced (Ref. 45). Therefore, the yield increase due to partial replacement of milk with fluid UF milk in all U.S. cheese production could save about \$172 million per year (\$0.02 per pound x 8.6 billion pounds).

This estimate may understate the potential cost savings; Fassbender (Ref. 49) states that a 10 percent replacement produces a yield increase of 25 percent, and an article from Dairy Management, Inc., states that a 10–15 percent replacement produces a yield increase as high as 18 percent (Ref. 50). In addition, the amount of rennet and starter cultures which are added to cheese milk can be reduced due to the higher solids content in the cheese milk. In one fluid UF milk research study at the Wisconsin Center for Dairy Research, a plant was able to reduce the rennet usage by 4 ounces per vat, for a total annual savings of over \$28,000 (Ref. 49). If we assume this plant is representative of all cheese manufacturing plants, then multiplying \$28,000 by the 403 cheese plants in 2002 (Ref. 45) gives a rough figure of \$11 million savings in coagulant usage annually. FDA notes that these estimates are uncertain and seeks comment on the cost savings from rennet and starter cultures.

Estimating the net social benefits from implementing UF technology requires subtracting out the private costs to firms of making the necessary capital investments. Milk is increasingly being ultrafiltered during the processing stage, usually at manufacturing plants or dairy cooperatives, so we assume that no capital investment in equipment by the cheese maker is needed to take advantage of UF technology for low level fluid UF milk concentration replacement (Ref. 48). Cheese producers can simply replace a portion of milk

with fluid UF milk purchased from a dairy processor without purchasing new equipment.

An early cost-benefit analysis of fluid UF milk production by Slack, et al. (Ref. 51), found that the benefits of UF milk production outweighed the costs for dairy farms with over 100 cows. However, this threshold has likely changed as the latest Pasteurized Milk Ordinance (April 2003 edition) loosened the restriction that allowed only single pass UF systems to now allowing for less expensive recirculating UF systems. Informal conversations with industry representatives revealed that the smallest single pass UF systems being marketed can process 300,000 lb of milk per day, the equivalent of production from almost 5,000 cows (300,000 lb is roughly 34,800 gallons, which at 7 to 8 gallons per cow per day, is 4,350 to 4,971 cows). Recirculating systems, on the other hand, are available for flow rates of 800 gallons per day, or production from approximately 100 cows (Ref. 52).

The costs of implementing fluid UF technology differ for four categories of dairy processors.

- If a processor already produces fluid UF milk, there is no additional cost to allowing the extended definition of milk in standardized cheese.
- If a processor collects milk from fewer than 100 cows, UF technology may not be economically feasible. If cheese producers switch their input purchases away from milk to fluid UF milk, there might be a redistribution of income away from these very small dairy processors. FDA believes that few, if any, milk processors will fall into this category. Even though there are many small dairy farms (72,070 in 2002) milk is not necessarily ultrafiltered on-farm. Instead, small dairy farms have the option of combining milk with other dairy farms in member-owned cooperatives or selling milk to proprietary operations

that combine milk from several farms for processing. The USDA defines a “small” dairy cooperative as handling less than 50 million lb of milk each year (Ref. 53), which is roughly the equivalent of milk from 2,000 cows per day and well above the 100 cow minimum.

- If a processor collects milk from more than 100 cows but less than 4,000 and is not currently producing fluid UF milk, then the cost of purchasing recirculating UF equipment ranges from \$175,000 to \$350,000 (Ref. 52).

- If a processor collects milk from 4,000 or more cows and is not currently producing fluid UF milk, then the cost of purchasing UF equipment ranges from \$350,000 for a recirculating system to \$1,372,500 for a single-pass system (Ref. 52).

Of the 1,153 dairy processors (which includes dairy cooperatives that process milk for members), an unknown portion would purchase UF technology in response to this proposed rule if finalized. In 2002, cheese production used 64,504 million lb of milk, which is approximately 61 percent of the 105,961 million lb used in all manufactured dairy products (Ref. 45). Therefore, we estimate that 61 percent of the dairy manufacturing plants process milk for cheese, for a total of 703 dairy plants. Given that at least 22 dairy manufacturing plants and 4 large dairy farms already produce fluid UF milk (Ref. 4), a total of 677 dairy processors may choose to purchase UF technology as a result of changing the definition of milk in § 133.3. Assuming that new purchases of UF equipment would more likely be recirculating systems, the total one time capital expenditure would range from \$118 to \$237 million. Given that the UF equipment depreciates over 7 to 14 years (Ref. 1), we estimated the annualized cost over a 10 year period. With a 3 percent interest rate, the annualized cost ranges from \$14 to \$28 million. With a 7

percent interest rate, the annualized cost ranges from \$17 to \$34 million. The annualized cost ranges indicate the capital expenditure ranges based on the equipment capacity needs described previously in this document.

Milk is produced daily, with the volume and composition varying both seasonally and daily. Demand for dairy products also varies both seasonally and daily, but demand variations are not correlated with supply variations (e.g., milk production peaks in the spring, but demand for milk and butter peaks in the fall months) (Ref. 53). Cheese producers, however, need to provide a consistent quality cheese, regardless of the day or season in which the inputs were produced. Replacing a given portion of milk with UF milk can eliminate the daily variation that occurs in milk composition by standardizing the ratio of casein to fat. However, fluid UF milk does not offer any price stability from seasonal fluctuations that occur in the supply and demand for both milk and cheese, since it cannot be stored past the short term in a liquid form. Nonfat dry milk has a shelf-life of 12 to 18 months (Ref. 50) and may offer more price stability from seasonal fluctuations.

The transportation and storage costs associated with fluid UF milk are lower than milk due to the removal of approximately two-thirds of the water, lactose, and ash during the filtration process (Ref. 48). The 2001 GAO Report cites a shipment of fluid UF milk by Select Milk Producers, Inc., in which the cost of transporting fluid UF milk was 73 percent lower than the cost of transporting milk. In this same year, milk hauling charges in the Upper Midwest Marketing Area (which includes California and Wisconsin, the top two milk producing states) averaged 17.1 cents per hundredweight (cwt) of milk (Ref. 54). A 73 percent price reduction in this average hauling cost lowers the cost of hauling fluid UF milk to an average of 4.62 cents per cwt. As stated

in the section I of this document, we assume that for approximately 80 percent of the cheese produced in the United States, fluid UF milk is used as a substitute in cheese production, not for milk, but for the baseline standardizing ingredient, NFDM. To calculate the transportation savings for these cheeses, we take the 64,504 million pounds of milk used in cheese production in 2002 (Ref. 45) and multiply by 80 percent to capture the amount shipped for American style natural cheeses. We then calculate 10 percent of this total to be replaced by fluid UF milk and convert it to cwt. This is the amount of milk that is subject to a 73 percent reduction in shipping costs, giving a total annual cost savings of about \$7 million as follows:

Calculation of Transportation Cost Savings for Fluid UF Milk Used in American Style Natural Cheese

80% X 64,504 million lb	=	51,603 million lb of milk shipped for American cheese production
10% X 51,603 million lb	=	5,160 million lb of milk filtered before shipment to cheese factory
5,160 million lbs/100 lb	=	51.6 million cwt of milk filtered before shipment
73% of 17.1 cents/cwt	=	\$0.13 savings per cwt of fluid UF milk shipped
\$0.13 X 51.6 million cwt	=	\$6.7 million

There would be an additional transportation and storage cost savings for the varieties of cheese that are well-suited to high concentrations of UF milk where replacement values are closer to 100 percent of the original milk. To get a potential range for what this cost savings would be, we calculated the transportation savings assuming that the remaining 20 percent of cheese production would use only UF milk for an upper bound and assuming only 2 percent of cheese production would replace 100 percent of milk in cheese production as a lower bound. The annual transportation savings here range from \$2 to \$17 million (See below).

Calculation of Upper Bound of Transportation Cost Savings for 100% Fluid UF Milk Replacement

20% X 64,504 million lb	=	12,901 million lb of milk shipped for all other cheese production
100% X 12,901 million lb	=	12,901 million lb of milk filtered before shipment to cheese factory
12,901 million lbs/100 lb	=	129 million cwt of milk filtered before shipment
73% of 17.1 cents/cwt	=	\$0.13 savings per cwt of UF milk shipped
\$0.13 X 129 million cwt	=	\$16.8 million

Calculation of Lower Bound of Transportation Cost Savings for 100% Fluid UF Milk Replacement

2% X 64,504 million lb	=	1,290 million lb of milk shipped for other cheese production
100% X 1,290 million lb	=	1,290 million lb of milk filtered before shipment to cheese factory
1,290 million lbs/100 lb	=	12.9 million cwt of milk filtered before shipment
73% of 17.1 cents/cwt	=	\$0.13 savings per cwt of UF milk shipped
\$0.13 X 12.9 million cwt	=	\$1.7 million

In terms of total transportation cost savings for all cheese production, this calculation gives an annual savings between \$9 and \$24 million for replacing milk with fluid UF milk in cheese production. While this is a cost savings over using milk in cheese production, it is not a savings over using NFDM. Reducing the moisture content of milk by two-thirds reduced the shipping costs by 73 percent, so it is reasonable to assume that NFDM with only 3.2 percent moisture (Ref. 40) and an increased shelf-life of 12 to 18 months (Ref. 50) would be significantly less expensive to ship and store than UF milk. Compared with the baseline then, these savings would be reduced by an amount in excess of \$7 million due to the actual increase in costs from replacing NFDM with fluid UF milk.

The total annual benefits from using fluid UF milk to make standardized cheeses are uncertain, partly because the number of additional plants that would use the UF technology is uncertain. The cost savings also depend on the size of the plants that decide to invest, the amount of milk which cheese producers replace with fluid UF milk, and whether fluid UF milk replaces milk or NFDM in the production process. If all dairy plants switch to UF technology, the yield and coagulant savings would be high, but investment costs would also rise. If most plants already use this technology, or decide against investing, the yield, coagulant, and transportation savings would be low. If NFDM is not extensively used in current cheese production, the transportation savings will be greater. Finally, if larger plants already have UF technology the total capital investment costs will decrease but yield increases will not be as dramatic as only smaller systems will potentially invest as a result of changing the definition.

In addition to the technical benefits in cheese production from allowing fluid UF milk to be used in standardized cheese production, amending the standards offers another economic benefit. Specifically, allowing fluid UF milk to be used as an ingredient in cheese would open the benefits of UF technology to a wider range of cheese manufacturers. Currently, fluid UF milk can be used in standardized cheese production only under "alternate make" procedures. Under the alternate make procedure provisions, manufacturers of cheese who purchase or produce milk in sufficient quantity to use UF technology may substitute the ultrafiltration of milk as a step in the cheese-making process as long as the final finished cheese has the same physical and chemical properties as the cheese produced under the procedure specified by the standard of identity. This provision only allows for the use of alternate procedures and not for alternate ingredients. Therefore, the use of UF technology must be within plant and within batch; fluid UF milk purchased from another plant, even within the same company, is considered an alternate ingredient. Allowing fluid UF milk as an ingredient effectively removes the barriers to shipment of fluid UF milk to cheese producers throughout the country and allows for greater competition in the market for cheese ingredients.

As stated previously in this document, approximately 22 dairy manufacturing plants and four large dairy farms produce UF milk. It is difficult to ascertain how much of the UF milk is being used within plants under alternate make procedure provisions, and how much is being shipped to outside plants. Few records are kept either by the USDA or trade associations regarding intermediate products like fluid UF milk (See GAO report). In 1996, the FDA permitted a single New Mexico plant to produce cold UF milk for shipment to a cheese-making plant in Minnesota for trial purposes only.

Subsequently, the New Mexico plant is said to have increased shipments of UF milk to 15 plants throughout the country (Ref. 49).

Allowing fluid UF milk to be used in standardized cheese production could significantly increase the number of plants using this cost-saving technology, particularly among smaller operations that cannot currently afford to purchase UF technology. These smaller cheese producers that cannot afford to filter milk as a step in the production process could purchase UF milk from a dairy processor. In 2002, there were 403 cheese plants and 1,153 dairy manufacturing plants spread across all fifty states (Ref. 45) but only 26 dairy plants and farms were producing UF milk. The supply of UF milk is restricted by the current definition, potentially increasing its cost as an input to cheese production.

Costs of Option 1: There are no health costs associated with the lower production costs of cheese made with fluid UF milk.

If consumers prefer cheese made under the existing milk definition and if they purchase cheese made from fluid UF milk believing it to be made from milk under the existing definition, there will be a small cost incurred by the consumer. However, even though the total dollar amount spent on cheese is large (in 2000, the retail price of 1 lb of natural cheddar cheese was \$3.83 (Ref. 55) and 8.2 billion lb of all cheeses (excluding cottage cheeses) were produced (Ref. 45), for total consumer expenditure of \$31.4 billion) the costs incurred from fluid UF milk are likely to be low because standardized cheeses do not tend to have credence attributes. Credence attributes are characteristics that consumers are willing to pay more for, even though they are not detectable after consumption (e.g., “dolphin-safe” tuna). The growth in the dairy products over the past 20 years has been largely attributed to increased demand for pizza

and fast food products that contain cheese, particularly Mozzarella and American cheese (Ref. 56). These are not the varieties of cheese that tend to be associated with cheese connoisseurs who demand purity in cheese ingredients. There is no evidence that consumers place a premium on cheeses made under the existing definition, in particular because cheese made with UF technology must have the same physical and chemical properties as cheese made under the existing milk definition and because an unknown quantity of cheeses produced in the United States are already made using UF technology under the alternate make procedure provisions.

The U.S. dairy market is regulated under both Federal and State regulations. The U.S. Government provides price supports for domestic milk production under the USDA's Commodity Credit Corp. A potential drop in the demand for milk as cheese producers switch to fluid UF milk could result in the market price dropping below the support price, thus forcing the government to purchase a larger amount of milk. However, fluid UF milk is produced by separating the components of milk. Therefore, any decrease in the domestic demand for milk resulting from the production and sale of fluid UF milk will be off-set by a decrease in the supply of milk, as dairies ultrafilter some of their milk instead of selling it directly. As a result, the quantity of milk purchased by the government is left unchanged. Stated another way, if cheese producers purchase fluid UF milk instead of other milk, the demand for milk from cheese producers will fall, while the demand for fluid UF milk from cheese producers will rise. As a result, the dairy processors who find it profitable to do so will decrease their supply of milk and instead ultrafilter the milk before they sell it to the cheese producer. If no dairy processors find it profitable to ultrafilter their milk before selling it, then cheese producers

will have no choice but to purchase milk, again leaving the amount purchased by the government unchanged.

In addition, the U.S. Government provides export subsidies under the Dairy Export Incentive Program. Fluid UF milk is less expensive to transport than milk under the standard definition of milk in cheese, leading to fears that expanding the use of fluid UF milk may increase imports and further decrease the demand for domestic milk. As of the first 9 months of 2002, all UF milk imported into the United States was in a dry powder form categorized as MPC (Ref. 57). Therefore, allowing the use of fluid UF milk as an ingredient in the standard of identity of cheese should not cause foreign-produced UF milk to replace domestic milk in cheese production or cause U.S. Government purchases under the Commodity Credit Corp. to rise.

Option 2: Allow fluid and dry UF milk in standardized cheese production

This option would allow UF milk either in fluid or spray-dried form. Dry UF milk is often referred to as MPC, though the definition of MPC is not consistently used and sometimes includes other dried filtered or concentrated milk products. This option differs from the baseline and Option 1 by substituting dry UF milk for NFDM or fluid UF milk as an ingredient in standardized cheeses.

Benefits of Option 2: The protein composition of dry UF milk ranges from 42 percent to 80 percent (Ref. 40), depending on the degree of concentration. In addition, as the protein concentration increases, the lactose content decreases from 46 percent to just 4.1 percent at the highest concentrations. Therefore, the supplementation of cheese milk with dry UF milk during the manufacturing process produces even larger yield increases per vat than fluid UF milk or NFDM, thus further spreading out fixed costs (labor, equipment,

physical facility) over more total weight of cheese. Given these larger cheese yield increases over fluid UF milk, it is safe to assume that the total yearly savings from using dry UF milk would exceed \$172 million. In addition, the amount of rennet and starter cultures which are added to cheese milk can be reduced due to the higher solids content in the cheese milk. The rough figure of \$11 million savings in coagulant usage annually calculated in Option 1 is applicable here as well.

Calculating the net social benefits to implementing UF technology requires subtracting out the private costs to firms of making the necessary capital investments. Similar to fluid UF milk, dry UF milk production occurs at the processing stage, usually at manufacturing plants or dairy cooperatives, so we assume no capital investment in equipment by the cheese producer is needed to take advantage of dry UF technology for low concentration UF milk replacement. Cheese producers can simply replace a portion of milk with dry UF milk purchased from a dairy processor without purchasing new equipment.

The costs of implementing dry UF technology varies among different types of dairy processors and will depend on their current production technology. If a dairy processor already produces UF milk and NFDM, there is no additional cost to allowing the extended definition of milk in standardized cheese. If a processor collects milk from fewer than 100 cows, it may not be economically feasible to implement the UF process, making dry UF milk production impossible even if the dairy processor has appropriate drying technology. If a dairy processor collects milk from 100 to 4,000 cows and is not currently producing UF milk, then the cost of implementing a UF system ranges from \$175,000 to \$350,000, depending on the size of the plant. If a processor collects milk from 4,000 or more cows and is not currently producing

UF milk, then the cost of purchasing UF equipment ranges from \$350,000 for a recirculating system to \$1,372,500 for a single-pass system. Using the same method as Option 1, the total one time capital expenditure for dairy processors who sell their products to cheese producers would be \$118 to \$237 million. If the dairy processor does not own a spray dryer, additional capital costs would be necessary, on the order of \$750,000 (Ref. 58). If half of all 703 dairy plants had to purchase this equipment, the one-time capital expenditure would grow by \$264 million for a total of \$382 to \$501 million. Given that the UF equipment depreciates over 7 to 14 years (Ref. 1), we estimated the annualized cost over a 10-year period. With a 3-percent interest rate, the annualized cost ranges from \$45 to \$59 million. With a 7-percent interest rate, the annualized cost ranges from \$54 to \$71 million. The annualized cost ranges indicate the capital expenditure ranges based on the equipment capacity needs described previously in this document.

Similar to NFDM, spray-drying UF milk significantly increases the shelf-life of the milk. Using such milk powders can eliminate the natural daily and seasonal variation that occurs in milk composition (by standardizing the ratio of casein to fat). In addition, the ability to store dry UF milk allows the cheese producer to offset the volatility of fresh milk prices (Ref. 9) and be better able to balance seasonal imbalances than milk or fluid UF milk.

The transportation and storage costs associated with dry UF milk are lower than either milk or fluid UF milk due to the removal of approximately 95 percent of the water, lactose, and ash (Ref. 40) during the ultrafiltration and subsequent drying processes. The moisture content of dry UF milk is similar to that of NFDM; therefore, it is reasonable to assume that shipping and storage costs would also be similar for replacing NFDM with dry UF milk in protein

standardization. If NFDM is not being used for protein standardization, then dry UF milk could offer substantial benefits compared to the transportation and storage of milk, possibly reducing these costs up to 95 percent.

A review of the literature found no manufacturers of dry UF milk in the United States; however, informal conversations with industry representatives revealed one joint venture in New Mexico that currently produces dry UF milk and possibly another firm in New York (Ref. 59). Little is known about the cost of producing dry UF milk, and why there is little to no U.S. production is a matter of some debate. The price floor set by the U.S. Dairy Price Support Program for NFDM is often cited as the cause. At the current levels of government purchase prices for milk protein, U.S. manufacturers of dry UF milk products would obtain the same or lower return per pound of protein than they would for producing NFDM. Given the higher manufacturing costs associated with UF technology, dairy producers in the United States are often better off producing NFDM and selling it to the government than producing dry UF milk products for cheese and other food uses (Ref. 60). Foreign firms who currently export dry UF milk to the United States have greater incentive to open their own plants in the United States, as it would reduce their transportation and tariff costs.

Costs of Option 2: There are no health costs associated with the lower production costs of cheese made with fluid or dry UF milk.

If consumers prefer cheese made under the existing milk definition and if they purchase cheese made from dry UF milk believing it to be made from milk under the existing definition, there will be a small cost incurred by the consumer. However, even though the total dollar amount spent on cheese is large (about \$31.4 billion in 2000) the costs incurred from dry UF milk are

likely to be low because standardized cheeses do not tend to have credence attributes and there is no evidence that consumers place a premium on cheeses made under the existing definition. Cheese made with UF technology must have the same physical and chemical properties as cheese made under the existing definition of milk within the cheese standards.

There is some concern over whether allowing dry UF milk (presumably imported from other countries) in the definition of milk in cheese would displace purchases of other dairy substitutes that are domestically produced. A drop in the demand for milk or NFDM as cheese producers switch to purchasing dry UF milk could result in the market price dropping below the support price, thus forcing the government to purchase a larger amount of milk. In addition, since dry UF milk is much less expensive to transport than milk and even fluid UF milk, expanding the use of dry UF milk may increase imports and further decrease the demand for domestic milk.

As in the case with fluid UF milk, if domestic production of dry UF milk increases as a result of the change in definition, any decrease in the domestic demand for milk resulting from the production and sale of dry UF milk would be offset by an decrease in the supply of milk, as dairies ultrafilter and dry some of their milk instead of selling it directly. As a result, the quantity of milk purchased by the government would be left unchanged. However, unlike fluid UF milk, dry UF milk is imported from other countries with no restrictions on the quantity and under a very low tariff rate (Ref. 60). The U.S. Government does not directly support the price of dry UF milk under the Credit Commodity Corp., purchases; however, if foreign-produced dry UF milk is substituted in production for NFDM and other milk products, increases in dry UF milk imports would cause government purchases of dairy products to

increase. If, on the other hand, allowing dry UF milk to be used in the production of standardized cheese causes domestic manufacturers of NFDM to produce dry UF milk instead, the amount of government purchases of NFDM may actually decrease as resources shift to the new product.

The inconsistency with which the term MPC is used makes it difficult to discern how much foreign-produced dry UF milk is being imported into FDA's Operational and Administrative System for Import Support (OASIS) database includes MPC as a separately identifiable product; however, many dried dairy substances other than dry UF milk are also included in this category, including milk protein isolate, whey protein concentrate, whey protein isolate, casein, milk protein stabilizer, emulsifier or binder, peptones, and total milk proteinate. Without a standard definition for MPC it is not clear that even imports labeled specifically as MPC are 100 percent dry UF milk.

In his analysis of MPC imports and the commercial disappearance of NFDM, Jesse (Ref. 60) separated the concentrated milk protein imports into the following four categories: MPC, Casein-MPC, Casein, and Caseinates/Other Casein Derivatives. Then, looking only at the category of MPCs, imports increased steadily between 1989 and 1997, at a rate of about 4,200 metric tons per year. From 1998 through 2000, imports started growing even more rapidly, with an average rate of growth at 18,000 metric tons per year (Ref. 60). However, 2001 and 2002 saw a reversal of this trend, with imports falling from 52,900 metric tons in 2000 to 28,500 metric tons in 2001 (Ref. 57). Estimates of 2002 imports were expected to total about 35,000 tons, about a 23 percent increase (Ref. 60). A news release published after the second quarter of 2003 by the National Milk Producers Federation states that MPC imports were up

39 percent from the first half of 2002 and approaching year 2000 levels (Ref. 61).

The impact of these imports increases in significance as USDA purchases more NFDM under the Commodity Credit Corp. The USDA had 1.2 billion lb of NFDM in warehouses, and program cost overruns were almost \$3 billion more than its original \$1.3 billion estimate in mid-2003 (Ref. 62). The negative impact on dairy production in the United States attributable to the MPC imports is uncertain, according to Jesse (Ref. 60) somewhere between “an amount much smaller than government purchases” of NFDM to an amount that “exceeds government purchases, and that excess cheese supplies augmented by MPC and other milk proteins have depressed the cheese market.” He estimated displacement of NFDM into government purchases at almost 430 million lb in 2002, though he added that his estimates “very likely err on the high side.” Bailey (Ref. 56), who separated “dry whey” and “casein” from MPCs, looked at this question from a cost angle. He estimated that MPC imports between 1996 and 2000 increased the cost the dairy price support program by about \$572 million (Ref. 56).

Option 3: Allow all filtration methods that result in a fluid milk product to be used in standardized cheese production

This option would allow fluid UF milk as well as milk processed with other filtration technologies, most notably microfiltration, as long as no nonmilk derived ingredients are added in the preparation of the liquid concentrates. This option differs from the baseline by permitting the substitution of fluid UF and MF milk for NFDM. This technology and the resulting product, sometimes referred to as Native Milk Casein Concentrates, is not currently available. However, the availability of the ingredient may be

driven by outside food manufacturers who fractionate milk proteins to harvest milk serum proteins leaving the native milk casein concentrate for sale to cheese manufacturers in the near future (Ref. 9).

Benefits of Option 3: The benefits from allowing fluid MF milk as an ingredient in cheese manufacture are similar to the benefits from allowing fluid UF milk due to similar levels of protein, lactose, and moisture (Ref. 63) (see table 1 of this document). There are other potential benefits from fluid MF milk that fluid UF milk does not offer. First, microfilters have larger pore structures than ultrafilters, allowing more whey proteins to pass through the membrane. If the cheese producers are purchasing MF milk, they will have less whey to remove in later steps of the cheese-making process. Second, some industry experts believe that MF is the new direction of cheese fortification process because it has the potential for continuous cheese making without vats for more varieties of cheese (Refs. 9 and 64).

Costs of Option 3: Because fluid MF milk is not yet available to cheese makers, it is difficult to determine how the costs would differ from NFDM. Because of the similar process to producing fluid UF milk, the costs are assumed to also be similar to Option 2.

Option 4: Allow all filtration methods that result in a fluid or dried milk product to be used in standardized cheese production

This option would allow milk used in the production of cheese to be supplemented with UF milk as well as milk forms derived from other filtration technologies, most notably microfiltration, as long as no nonmilk derived ingredients had been added in the preparation of these liquid or dried concentrates. This option differs from the baseline by substituting both fluid and dry UF and MF milk for NFDM as the protein standardization ingredient.

As with fluid MF milk, this technology and the resulting product, sometimes referred to as Native Milk Casein Concentrates, is not currently available. However, the availability of the ingredient may be driven by outside food manufacturers who fractionate milk proteins to harvest milk serum proteins, leaving the native milk casein concentrate for sale to cheese manufacturers in the near future (Ref. 9).

Benefits of Option 4: The benefits of allowing fluid or dry MF milk as an ingredient in cheese build on the benefits of Option 3, which allows for fluid MF milk. In addition to those benefits, allowing dry MF milk has decreased transportation and storage costs similar to NFDM and dry UF milk.

Costs of Option 4: Because neither fluid nor dry MF milk is available to cheese producers, we are unable to estimate how costs would differ from NFDM. Dry MF milk, being similar in manufacture to dry UF milk, would be subject to similar costs, including foreign trade and domestic purchase adjustments.

Option 5: Allow all milk and products obtained from milk to be used in cheese production, in agreement with the Codex general standard for cheese

This option would allow milk to be manufactured with “milk and/or products obtained from milk” and would mirror the Codex general standard for cheese (Ref. 25). This option differs from the baseline by allowing any milk derived ingredient to be used as either the sole ingredient or the protein-standardizing replacement ingredient in cheese production. This option would include isolates of casein that contain up to 94 percent protein and little to no lactose. These isolates are not currently manufactured in the United States, but have been used in other countries as a fortification ingredient (Ref. 9). This

option would also allow for dry blends of different milk derived ingredients, including NFDM, dry UF milk, isolated casein, and whey protein concentrate.

Benefits of Option 5: The benefits to opening the standard to all “milk and/or products obtained from milk” are not certain, but would allow cheese producers full freedom in choosing inputs to maximize their own production yields and profits.

Costs of Option 5: The costs to opening the standard to all “milk and/or products obtained from milk” are not certain. There may be domestic and international market adjustments leading to U.S. Government purchases of domestic dairy products.

D. Summary of Costs and Benefits

The total annual costs and benefits from amending the definition of milk used to produce standardized cheeses are uncertain, though FDA does not have concerns from a food safety standpoint. The uncertainty stems from several diverse factors:

- The number of plants that would implement UF or other filtration technology,
- The number of plants that already use UF technology,
- The number of plants that already use spray-drying technology,
- The size of the plants that would decide to invest in new technology,
- The percent of milk that cheese producers would replace with UF milk in cheese making, and
- Whether UF milk replaces milk or NFDM in the production process

Table 2 of this document highlights the quantified annual costs and benefits of Options 1 through 5 using the assumptions and calculations described in the text.

TABLE 2.—COSTS AND BENEFITS SUMMARY

	Option 1	Option 2	Option 3	Option 4	Option 5
Annualized Investment	\$14–\$28 million ¹ \$17–\$34 million ²	\$45–\$59 million ¹ \$54–\$71 million ²	Unknown	Unknown	Unknown
Yield Increase	\$172 million	\$172 million	Unknown	Unknown	Unknown
Transportation Savings	< \$9 to \$24 million	> \$9 to \$24 million Similar to Option 1	Similar to Option 2	Unknown	
Rennet & Starter Savings	\$11 million	\$11 million	Unknown	Unknown	Unknown
Benefits (net savings in production costs)	\$164–\$193 million ¹ \$158–\$190 million ²	\$133–\$162 million ¹ \$121–\$153 million ²	Unknown	Unknown	Unknown
Government Programs	No increase in government purchases or trade impacts	Potential for increase in government purchases of NFDM	Unknown	Unknown	Unknown
Costs (change in government program costs)	None	Uncertain	Unknown	Unknown	Unknown

¹ At 3 % interest.² At 7 % interest.

FDA does not currently have a best estimate on the cost savings of this proposed rule and seeks comment on all areas of uncertainty listed previously in this document. FDA believes Options 1 and 2, if implemented, would lead to social benefits potentially as high as \$190 million at a 7 percent annualized investment rate (\$193 million at 3 percent) and \$153 million (\$162 million at 3 percent), respectively. Options 3 through 5 are difficult to quantify based on the smaller amount of research into new filtration and separation technologies in the dairy industry. These options lead to increasingly greater flexibility for cheese producers to maximize their own production yields and profits and have the potential to provide benefits to the cheese industry in the future.

IV. Small Entity Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effects of the rule on small entities. FDA finds that

this proposed rule would have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) considers a dairy manufacturer, which includes cheese manufacturers, to be small if it employs fewer than 500 workers. Table 3 of this document lists the dairy manufacturing statistics by employment size from the U.S. Census Bureau's 1997 Economics Census for the three industries most likely to be impacted by this proposed rule. The total number of firms listed in table 3 of this document is different from earlier parts of the analysis because the earlier estimates were derived from 2002 USDA data but the most recent Economic Census data available is for 1997.

TABLE 3.—DAIRY MANUFACTURING STATISTICS BY EMPLOYMENT SIZE

	Total Number Of Firms	Number of Firms with Less than 500 Employees	Percent of Industry that is "Small"
Cheese Manufacturing	524	518	98.9
Fluid Milk Manufacturing	612	605	98.9
Dry, Condensed, and Evaporated Dairy Manufacturing	213	208	97.7

Source: U.S. Census Bureau, 1997 Economic Census June 24, 1999 Manufacturing—Industry Series.

Based on the SBA definition of small business for the dairy manufacturing industries, almost all dairy and cheese manufacturers qualify. However, Blayney and Manchester found that large dairy manufacturing companies and cooperatives, those percent with food and nonfood sales in 1998 of \$800 million or more, accounted for almost 70 percent of the industry (Ref. 65). Of this 70 percent, large proprietary companies accounted for 42 percent and large cooperatives for 27 percent. The remainder of the industry was divided between smaller companies, including cooperatives (Ref. 65).

The dairy industry in the United States exhibits substantial economies of scale and, historically, small dairy farms have found ways of combining their resources to be able to compete in the industry. The 1960s saw a wave of mergers and consolidations, leading to almost a complete conversion to "bulk

handling and processing” of milk at plants in the 1970s. This trend has continued with ever-decreasing numbers of processors handling ever-increasing volumes of milk (Ref. 47).

FDA believes that if cheese manufacturers demand UF milk, dairy cooperatives will adjust in order to keep themselves and their individual members viable in the market. In 1997, the last year the USDA did a comprehensive survey of dairy cooperatives, dairy cooperatives handled 83 percent of all milk delivered to plants and dealers in the United States, and 98 percent of the milk received by cooperatives came directly from member producers (Ref. 53). These cooperatives are diverse in size, but the average handles 564 million lb annually, well above the 2.2 million lb requirement of production from 100 cows. According to the National Milk Producers Federation (NMPF) Web site, the average U.S. dairy cow produces about 7 gallons of milk per day (Ref. 66). To calculate the minimum weight to make UF technology financially feasible, we multiplied 100 cows by 7 gallons per day by 365 days per year to get 255,500 gallons per year. We then multiplied the product by 8.62 lb per gallon (NMPF Web site) to get 2,202,410 lb per year. FDA seeks comment on the financial burden investing in UF technology imposes on dairy processors and cheese manufacturers, particularly small entities.

In addition, small milk operations combined in cooperatives may be able to gain additional benefits from UF technology if they are able to market their products in a larger geographic region as a result of the lower shipping costs. This issue may be important if dairies develop in remote locations around the country as Mermelstein (Ref. 48) has suggested, or if there is a geographical shift in the production of either cheese or its components. Milk production

in the West, as a percentage of total U.S. production, has increased, and there is some concern that Midwestern cheese producers will become “milk-starved” (Ref. 49). National Agricultural Statistics Services data over the past 9 years has shown a significant increase in milk production in the West, up to 38 percent of the U.S. total in 2001 and 2002. However, these data also show a significant increase in cheese production in the Western States over this same time period, up to 37 percent in 2001 and 38 percent in 2002 (Ref. 67). The significantly lower hauling costs for filtered milk may enable small milk processors and cheese producers to ship ingredients over longer distances to meet manufacturing needs.

V. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (annually adjusted for inflation) in any 1 year.” The current inflation-adjusted statutory threshold is \$113 million. FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VI. Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) Major Rule

The SBREFA (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of \$100 million; a major increase in cost or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based

enterprises in domestic or export markets. In accordance with the SBREFA, the Office of Management and Budget (OMB) has determined that this proposed rule is a major rule for the purpose of congressional review.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule would have a preemptive effect on state law. Section 4 (a) of the Executive Order requires agencies to “construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(1) provides that:

* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g). * * *

This proposed rule makes changes to the general provisions related to the standards of identity for cheeses and related cheese products. Although this rule would have a preemptive effect in that it would preclude States from promulgating requirements for standardized cheese and cheese products that are not identical to the standards as amended by this proposal, this preemptive effect is consistent with what Congress set forth in section 403A of the act.

Section 4(c) of the Executive Order further requires that “any regulatory preemption of State law shall be restricted to the minimum level necessary”

to achieve the regulatory objective. Under section 401 of the act (21 U.S.C. 341), “[w]hen in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food * * * a reasonable definition and standard of identity. * * *” Further, section 4(e) provides that “when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.” FDA is providing an opportunity for State and local officials to comment on this rulemaking. For the reasons set forth above, the agency believes that it has complied with all of the applicable requirements under the Executive order.

In conclusion, FDA has determined that the preemptive effect of the proposed rule would be consistent with Executive Order 13132.

VIII. Environmental Impact

We have determined under 21 CFR 25.32(p) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by OMB under Paperwork Reduction Act of 1995 is not required.

X. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are

to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Cheryan, M., Ultrafiltration and Microfiltration Handbook, 2d ed., CRC Press LLC, Boca Raton, FL, chapters 1 and 3 and pp. 349–369, 1998.
2. Rosenberg, M., “Current and Future Applications for Membrane Processes in the Dairy Industry,” *Trends in Food Science and Technology*, 6:12–19, 1995.
3. Smith, K.E., Background on Milk Protein Products, *Dairy Proteins*, prepared by the Wisconsin Center for Dairy Research and the Wisconsin Milk Marketing Board, 2001.
4. GAO report, “Dairy Products: Imports, Domestic Production, and Regulation of Ultra-filtered Milk,” March, GAO–01–326, 2001.
5. Letter to FDA from Mr. Ted Jacoby, Jr., T.C. Jacoby & Company, Inc., May 1, 1996
6. Letter to Mr. Ted Jacoby, Jr., T.C. Jacoby & Company, Inc., from FDA, October 21, 1996.
7. Letter to Mr. F. Tracy Schonrock, USDA from FDA, October 21, 1999.
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List of Subjects in 21 CFR Part 133

Cheese, Food grades and standards, Food labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and re-delegated to the Director of the Center for Food Safety and Applied Nutrition, it is proposed that 21 CFR part 133 be amended as follows:

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

1. The authority citation for 21 CFR part 133 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

2. Section 133.3 is amended by revising paragraphs (a) and (b) and by adding new paragraphs (f) and (g) to read as follow:

§ 133.3 Definitions.

(a) *Milk* means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, reconstituted milk, and dry whole milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added. For the purposes of this part, wherever the term “milk” appears in the individual standards for cheeses and related cheese products, ultrafiltered milk as described in paragraph (f) of this section, may be used.

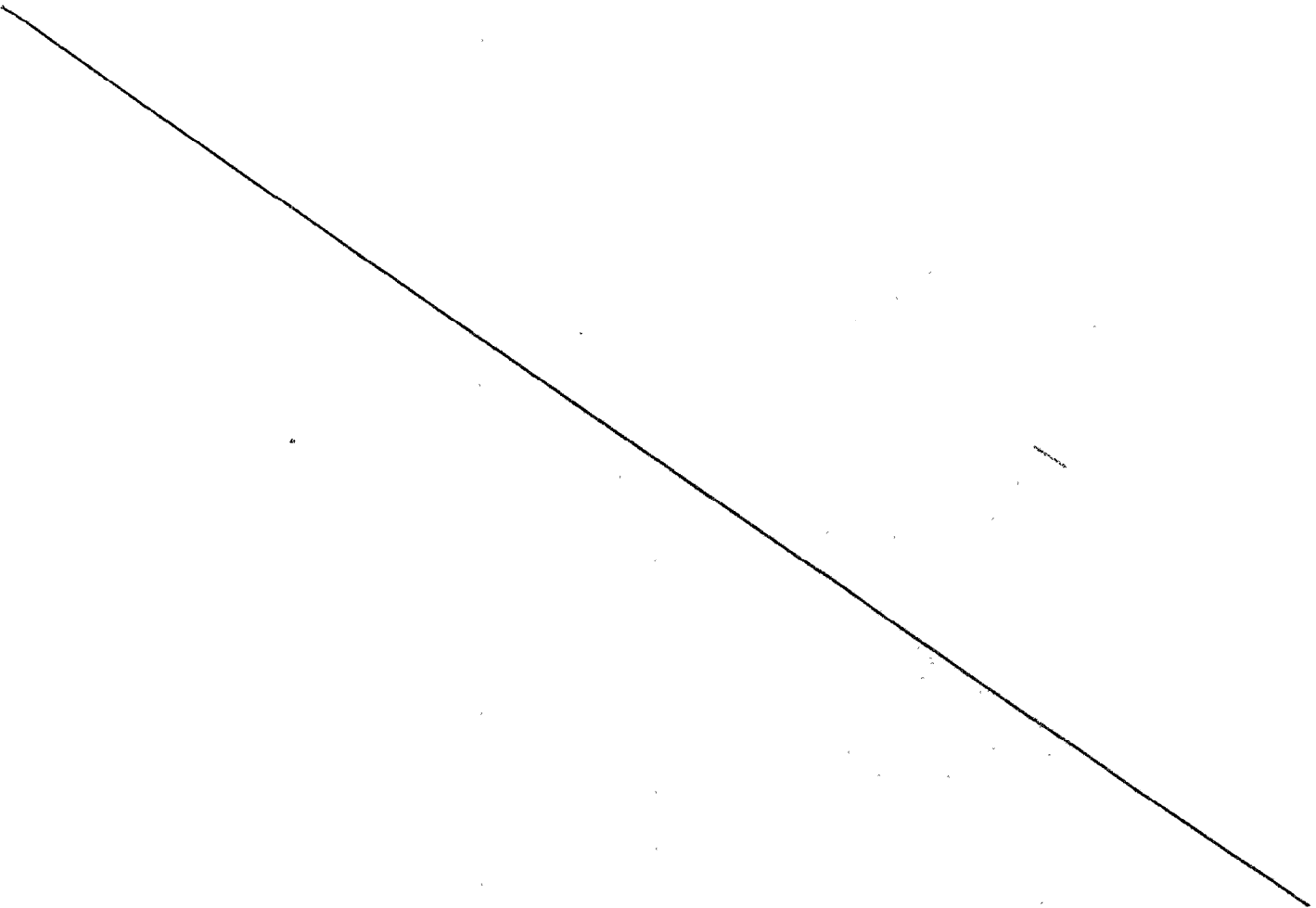
(b) *Nonfat milk* means skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added. For the purposes of this part, wherever the term “nonfat milk” appears in the individual standards for

cheeses and related cheese products, ultrafiltered nonfat milk as described in paragraph (g) of this section, may be used.

* * * * *

(f) *Ultrafiltered milk* means raw or pasteurized milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein:whey protein ratio of the milk and resulting in a liquid product.

(g) *Ultrafiltered nonfat milk* means raw or pasteurized nonfat milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein:whey protein ratio of the nonfat milk and resulting in a liquid product.



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